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| EXAMINER |
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BEISNER, WILLIAM H

| ART UNIT | PAPER NUMBER |
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1744

| MAIL DATE | DELIVERY MODE |
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06/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/922,013

Applicant(s)

RUTENBERG ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005 and 07 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-20,23,24 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20,23,24 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/5/05 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 18-20, 23, 24 and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First, independent claim 28 is indefinite because the claim fails to positively recite structural cooperation between the recited brush means and the analytical apparatus. It appears from the disclosure that the brush means and analytical apparatus do not function as a single entity and/or system. It is suggested that the claim be changed to a kit claim in view of the lack of structural cooperation discussed above with respect to the recited brush means and analytical apparatus.

Claim 28, line 6, "said uppermost" lacks clear antecedent basis. It appears that the language should be "said uppermost surface".

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Claim 28 is also indefinite because it is not readily clear from the instant specification as to what structural elements, if any, correspond to the positively recited “analytical apparatus”, “means to determine” and “means to conduct DNA ploidy”. Review of the instant specification fails to clearly set forth what structures, if any, correspond to the intended functions associated with the means-plus-function language recited in claim 28. It is not clear if a device that includes an imaging system and a computer would structurally meet the instant claim language.

In claim 18, “said computer” lacks antecedent basis.

Claims 19, 20, 23 and 27 are indefinite because it is not clear what additional structure is being recited, if any at all.

In claim 26, “said completer” lacks antecedent basis.

Claim Rejections - 35 USC § 103

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 18-20, 23-24 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al.(US 6,137,899) in view of Lonky et al.(US 6,258,044).

The reference of Lee et al. discloses a system (500) for detecting precancerous and cancerous cells in a cell population. The system includes an analytical apparatus including imaging (502) and image processing (536). The imaging and image processing components morphologically select individual atypical (abnormal) cells from the cell population (See classifiers 92, 94, and 96 in Figure 4A). Note the reference discloses that at any stage, objects that are classified as normal or artifact are not classified further (See column 10, lines 54-56). After passing through stage 1, 2 and 3, abnormal (atypical) cells are further classified a means to conduct DNA ploidy quantization of the selected atypical cells (See ploidy classifier 100). Note in view of the indefiniteness with respect to the means-plus-function discussed previously, the imaging system and image processing of Lee et al. is considered to be structurally the same as that instantly claimed. Additionally note, statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 28, while the reference of Lee et al. discloses a PAP smear-type of analysis, the reference does not disclose the use of a sample collection brush with the system.

The reference of Lonky et al. discloses that the use of a brush means to collect a cell population for cytological analysis is well known in the art (See brush means, 20). The reference

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of Lonky et al. discloses that the disclosed brush is capable of collecting cell samples from epithelial tissue having an uppermost surface and tissue containing areas below the uppermost surface (See the abstract and entire disclosure).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the PAP smear to be used in the system of the primary reference using the sampling brush of the reference of Lonky et al. for the known and expected result of providing a means recognized in the art for preparing a cell sample specimen. The brush of Lonky et al. provides the advantage that it allows collected samples to include cells in addition to spontaneously exfoliated cells (See column 4, lines 5-25 and column 4, lines 44-54).

With respect to the method steps required of claims 18-20, 23 and 26-28, in the absence of further positively recited structure, the system of Lee et al. is considered to be capable of performing the method steps recited in these claims.

With respect to claim 24, the brush disclosed by Lonky et al. removes cells from at least two layers of epithelial tissue.

7. Claims 18 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al.(US 6,137,899) in view of Lonky et al.(US 6,258,044) and Rutenberg et al.(US 5,740,270).

The combination of the references of Lee et al. and Lonky et al. has been discussed above.

Claim 18 differs by reciting that the locations of the atypical cells are retrieved by the analytical apparatus for cell-by-cell analysis.

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The reference of Rutenberg et al. discloses a system for classification of cells in a cell sample that employs image processing which is similar to that of the primary reference of Lee et al. The reference of Rutenberg et al. discloses that the locations of the cells which are selected as atypical by the primary and secondary classifiers are stored in the computer system (20) such that tertiary classification can be performed by a person trained to detect truly abnormal cells (See column 8, lines 35-60).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the modified primary reference with a tertiary classification means as taught by Rutenberg et al. for the known and expected result of allowing a person trained to detect abnormal cells can confirm the results of the automated classification system.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al.(US 6,137,899) in view of Lonky et al.(US 6,258,044), Rutenberg et al.(US 5,740,270) and Bacus (US 5,526,258).

The combination of the references of Lee et al., Lonky et al. and Rutenberg et al. has been discussed above.

The above claim differs by reciting that the computer plots a histogram to show DNA ploidy.

The reference of Bacus discloses that when using a computer to perform DNA ploidy, it is conventional in the art to employ histograms to show DNA ploidy of selected cells (See Figures 3-6 and 12).

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In view of this teaching, when performing DNA ploidy analysis, it would have been obvious to one of ordinary skill in the art to program the computer so as to display the results in the form of histograms for the known and expected result of providing a conventional means in the art to display DNA ploidy information which has been determined by a computer. This provides a visual indication of ploidy for the operator of the automated system.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al.(US 6,137,899) in view of Lonky et al.(US 6,258,044), Rutenberg et al.(US 5,740,270) and Lee et al.(US 5,787,189).

The combination of the references of Lee et al., Lonky et al. and Rutenberg et al. has been discussed above.

Claim 20 differs by selecting atypical cells using reference cells chosen from the same population.

The reference of Lee et al. ('189) discloses that in an automated cell analysis and imaging system, it is known to employ a reference cell classifier which employs reference cells from the population of cells to be classified and employs the reference cells data when determining atypical cells (See column 4, lines 20-26 and column 5, lines 20-29).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a reference cell classifier in the system of the modified primary reference for the known and expected result of providing a means recognized in the art for compensating for differences in slide preparation (See column 1, lines 12-34).

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10. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al.(US 6,137,899) in view of Lonky et al.(US 6,258,044) and Hemstreet, III et al.(US 5,733,721).

The combination of the references of Lee et al. and Lonky et al. has been discussed above.

The above claim differs by reciting that the system further includes the use of molecular diagnostic techniques on the atypical cells.

The reference of Hemstreet, III et al. discloses that it is known in the art to employ molecular diagnostic techniques when screening cell samples for cancer. See the entire disclosure. The reference discloses that morphological and ploidy analysis techniques can provide abnormal cells which are not cancerous (See column 2, lines 1-16).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to supplement the classification processes of the modified primary reference using a molecular diagnostic technique disclosed by the reference of Hemstreet, III et al. for the known and expected result of providing an additional level of confirmation of cancerous or precancerous cells since morphological and ploidy techniques are capable of indicating abnormal cells which are not precancerous or cancerous.

Response to Arguments

11. With respect to the rejection of claims 18-20, 24 and 26-29 under 35 USC 112, second paragraph, Applicants argue (See page 3 of the response filed 8/8/05) that the amendments to the claims address the issues raised in the rejection.

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In response, new grounds of rejection have been made in view of the previous claim language and newly recited claim language.

12. With respect to the rejection of claims 18-20, 24 and 26-29 under 35 USC 103 over the reference of Lee et al. ('899) in view of Lonky ('044) alone and further in view of additional references, Applicants argue that the rejections are improper for a number of reasons.

With respect to claims 28 and 24, Applicants argue (See page 4 of the response dated 8/8/05) that the combination of the references of Lee et al. and Lonky do not meet the instant claim language because the references do not conduct DNA ploidy quantization from the most atypical appearing cells.

In response, in the absence of further positively recited claim language that clearly defines the structure of the claimed system, the Examiner is of the position that the structure resulting from the combination of the references of Lee et al. and Lonky structurally meets the instant claim language because the system of Lee et al. is capable of operating in the manner required of claim 28. Note a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With respect to claims 18-20 and 27, Applicants argue (See pages 5-6 of the response filed 8/8/05) that the combination of the additional references of Rutenberg, Bacus and/or Hemstreet fails to meet the instant claim language because the combined teachings of the references do not result in the same methods required of the instant claims.

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In response, in the absence of further positively recited claim language that clearly defines the structure of the claimed system, the Examiner is of the position that the structure resulting from the combination of the references of Lee et al. and Lonky structurally meets the instant claim language because the system of Lee et al. is capable of operating in the manner required of claim 28. Note a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

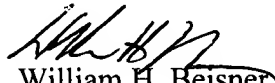
Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB